

Briefing

COVID-19 Vaccine Portfolio – Management of Novavax Delivery Schedule

Date due to MO: 17 May 2021 **Action required by:** 20 May 2021

Security level: ~~Commercially Sensitive~~ **Health Report number:** 20211095

To:

- Rt Hon Jacinda Ardern, Prime Minister
- Hon Grant Robertson, Minister of Finance
- Hon Chris Hipkins, Minister for COVID-19 Response
- Hon Andrew Little, Minister of Health
- Hon Nanaia Mahuta, Minister of Foreign Affairs
- Hon Aupito William Sio, Minister for Pacific Peoples
- Hon Dr Ayesha Verrall, Associate Minister of Health
- Hon Peeni Henare, Associate Minister of Health

Contact for telephone discussion

Name	Position	Telephone
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Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)

Minister's office to complete:

- | | | |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Decline | <input type="checkbox"/> Noted |
| <input type="checkbox"/> Needs change | <input type="checkbox"/> Seen | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn | |

Comment:

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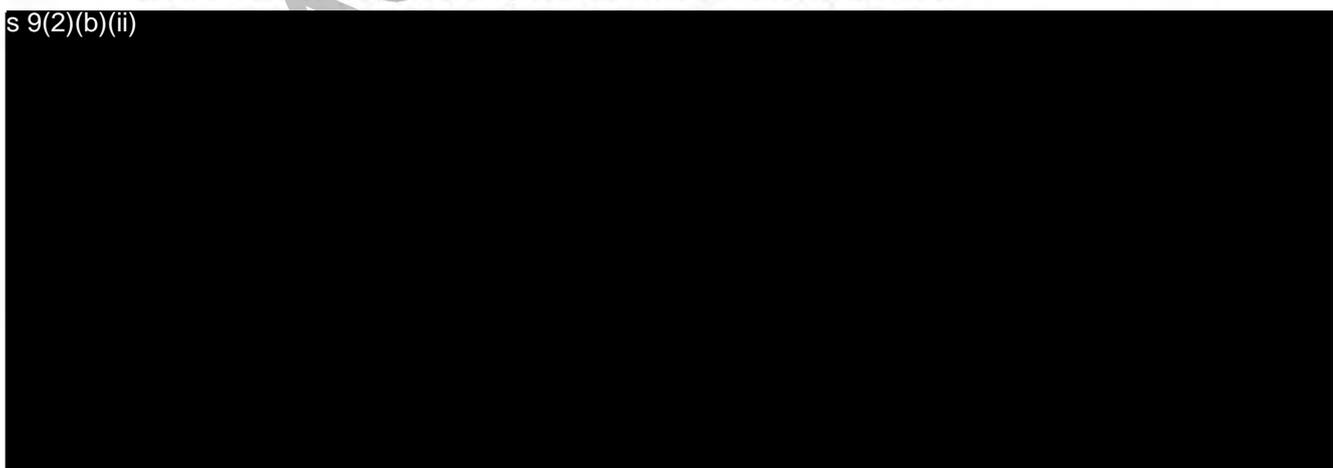
Purpose of report

This briefing provides an update of the expected Novavax vaccine delivery schedule and seeks your decision on the approach to managing these courses, secured as part of our COVID-19 vaccine portfolio.

Summary

1. New Zealand currently has four COVID-19 vaccines in its portfolio in an endeavour to secure access to a safe and effective vaccine. To date, the COVID-19 Immunisation Programme has been based around the Pfizer vaccine, which is the only COVID-19 vaccine currently approved by Medsafe for use in New Zealand.

s 9(2)(b)(ii)



4. As more information and evidence emerges on vaccines and COVID-19, decisions on managing the portfolio to support our COVID-19 immunisation needs will begin to

factor in longer term considerations, such as wider eligible population groups, and the possible need for booster vaccines and/or updated vaccines to improve protection against variants.

s 9(2)(b)(ii)

s 9(2)(g)(i)

7. The recommended approach to the Novavax vaccine is for it to be used to manage downstream risks s 9(2)(b)(ii)
8. Additionally, this decision would mean New Zealand would still have access to a vaccine that could offer full population coverage while we wait for more certainty around vaccination needs for 2022 and outyears.

s 9(2)(b)(ii)

Recommendations

We recommend you:

- a) **Note** that it was agreed [HR 20210291 refers] that the vaccine portfolio will:
 - i. adjust so that decisions on use reflect where we have greater confidence in vaccine candidate/s;
 - ii. adjust to increase the success of the COVID-19 Immunisation Programme delivery, in particular to make the planning or logistics simpler by using one or two vaccines; and
 - iii. shift the wider portfolio to manage risk downstream or specific risks associated with the use of a vaccine (for example, vaccine failure or delivery risk)

s 9(2)(b)(ii)

Rt Hon Jacinda Ardern

Prime Minister

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Hon Chris Hipkins

Minister for COVID-19 Response

18/5/2021
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Hon Grant Robertson

Minister of Finance

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Hon Andrew Little

Minister of Health

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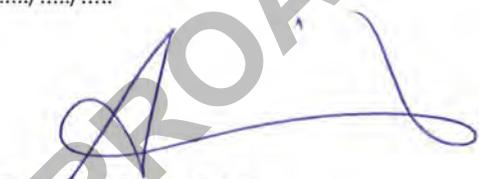
Associate Minister of Health

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Hon Peeni Henare

Associate Minister of Health

...../...../.....



Dr Ashley Bloomfield

Director-General of Health

17/5/21
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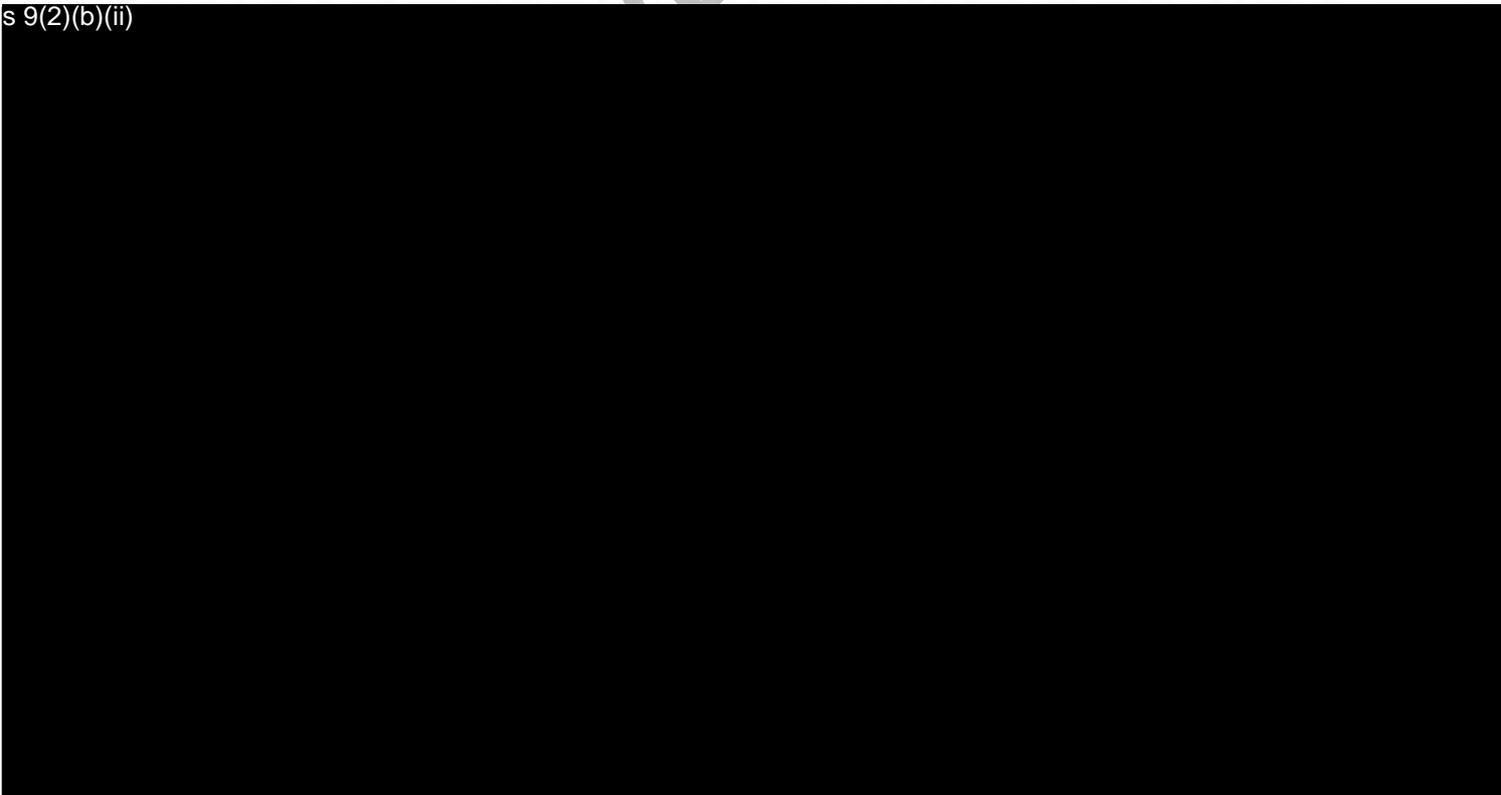
COVID-19 Vaccine Portfolio – Update April 2021

Context

10. In May 2020, Cabinet agreed to the COVID-19 Vaccine Strategy [CAB-20-MIN-0382 refers]. The objective of this strategy is to secure access to sufficient quantities of safe and effective COVID-19 vaccines, in order to implement our preferred COVID-19 Immunisation Programme at the earliest possible time. In parallel, the Strategy seeks to support access to safe and effective vaccines in Polynesia.
11. Achieving the objectives of the Strategy will contribute to the following outcomes:
 - a. sufficient supply of a safe and effective vaccine to achieve population immunity to COVID-19, affordably
 - b. protection for Māori, Pacific peoples and population groups at particular risk from COVID-19
 - c. full cultural, social and economic recovery from the impacts of COVID-19
 - d. recognition of New Zealand as a valued contributor to global wellbeing and the COVID-19 response.
12. We have deliberately taken a portfolio approach to manage the risk of vaccine development failure and to support the success of our COVID-19 Immunisation Programme [CAB-20-MIN-0508].

COVID-19 Vaccine Portfolio

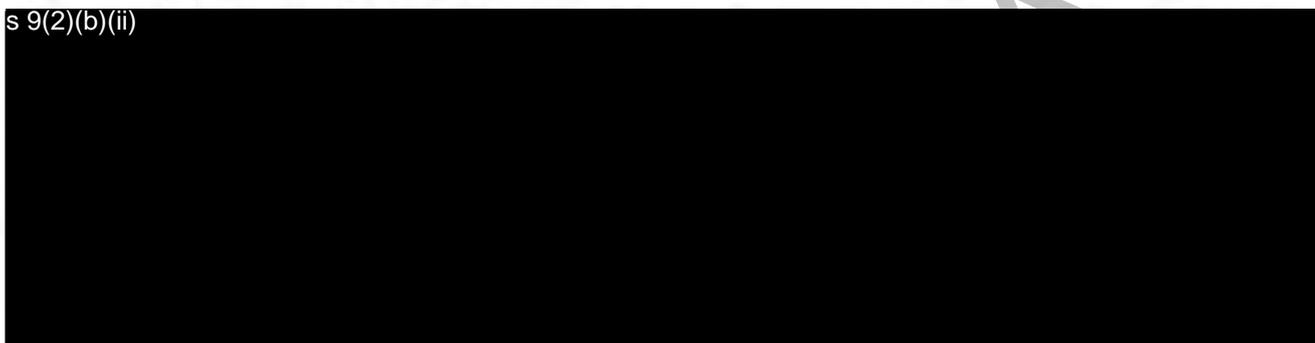
s 9(2)(b)(ii)



14. To date, the COVID-19 Immunisation Programme has been based around the Pfizer vaccine, which is the only COVID-19 vaccine currently approved by Medsafe for use in New Zealand. There will be enough doses of the Pfizer vaccine delivered in 2021 to vaccinate all eligible New Zealanders.
15. Even as the COVID-19 Immunisation Programme progresses with utilisation of the Pfizer vaccine, the Ministry of Health considers that a vaccine portfolio approach remains relevant. However, the context is shifting as more information about the relative performance of different vaccines emerges, as well as the increasing certainty of supply.
16. As more information and evidence emerges on vaccines and COVID-19, decisions on managing the portfolio to support our COVID-19 immunisation needs will begin to factor in longer term considerations, such as wider eligible population groups, and the possible need for booster vaccines and/or updated vaccines to improve protection against variants.

Recent Portfolio Management Decisions

s 9(2)(b)(ii)



19. Following a regulatory decision from Medsafe, expected in late May, further advice will be provided to you seeking a decision on how to utilise the s 9(2)(b) courses of Janssen vaccine.

s 9(2)(b)(ii)



21. Managing risks associated with a Pfizer based programme and any potential downstream risk needs to be balanced against ensuring that we fully utilise vaccine candidates in our portfolio when it is timely to do so. In practice, this means considering:
 - a. which vaccine candidates we maintain access to that will help manage risks for the Immunisation Programme; and
 - b. which vaccine candidates would support global efforts and equitable access to vaccines.

22. Timely decisions will reduce the likelihood that New Zealand takes receipt of vaccines we don't intend to use and reduce the overall cost to the Crown.

Management of the Novavax Vaccine Delivery Schedule

Current situation

23. The New Zealand Government has entered into an APA with Novavax s 9(2)(b)(ii)

24. The Novavax vaccine is a protein subunit vaccine, which has been demonstrated in early clinical trials to be effective at preventing symptomatic COVID-19 infection at a similar rate as the Pfizer vaccine, including against current variants.

s 9(2)(b)(ii)

26. This interim delivery schedule is indicative only, and delivery of any doses to New Zealand is subject to prior Medsafe approval. It is not yet known when a regulatory decision is expected from Medsafe. To date, the Novavax vaccine has not been approved for use or granted emergency use authorisation in any jurisdictions.
27. Novavax has stated publicly that it has pushed back timelines for hitting early production targets due to supply shortages of manufacturing ingredients. These manufacturing delays may impact on the interim delivery schedule above, although Novavax is yet to provide any updates for New Zealand.

s 9(2)(b)(ii)

41. There is no strong rationale supporting the use of the Novavax vaccine alongside a primarily Pfizer based Immunisation Programme, as it is unlikely that the regulatory approval timing will enable a delivery schedule that would be in advance of the Q3-4 additional courses that we expect to receive for the Pfizer vaccine for the start of the general population roll out of our COVID-19 Immunisation Programme.
42. It is also not likely that the Novavax vaccine would assist with managing any supply risks with the Pfizer vaccine in 2021, given we have limited certainty around timing or supply. This would leave the Janssen vaccine as the only vaccine option in our portfolio to potentially manage a supply disruption of the Pfizer vaccine.

s 9(2)(b)(ii)



Equity

s 9(2)(b)(ii)



51. Consideration of global access to vaccines is also of high importance to ensure New Zealand can continue to be a valued contributor to global wellbeing and the overall COVID-19 response.

Next steps

s 9(2)(b)(ii)



53. We intend to provide clear communications that any decision to defer a vaccine in our portfolio is not based on concerns around the efficacy, effectiveness or safety of vaccines. There is only limited science and clinical information, and decisions are being made to manage the risk of potential future immunisation needs and to focus the New

Zealand programme where we do have more certainty of delivery schedules or regulatory status.

s 9(2)(b)(ii)

55. Further advice will be provided in due course, seeking a decision on how to utilise the s 9(2)(b)(ii) courses of Janssen vaccine.

ENDS.

PROACTIVELY RELEASED